Regarding question 3 of 5, submitted for public comment:

3. What role does the concept of "value" play in this debate and how should an innovative therapy's value be represented in its price?

Value based pricing is an attractive but deceiving mechanism, which **distracts from the main issue of the high and rising costs of pharmaceuticals**. We cannot afford to waste time on these types of arguments, because we cannot hold the status quo much longer.

High prices result from **patent monopolies** that **necessitate scarcity** and the **restriction of the benefits of research** for the sake of extracting maximum profits from sick people.

Problems with Value Based Pricing

-**Price matters**. It matters to the governments who would go bankrupt by treating all their sick people. It matters to the many, many uninsured individuals both in the US and abroad who can never dream of paying the sticker price.

-Price even matters to the insurance companies in the US who **cannot cover people with other diseases, if they have to pay for a very expensive new drug** for another disease. (*i.e. If new Hep C DAAs are just under the price of a liver transplant, and we now have the opportunity to cure everyone with Hep C by giving them these drugs, what does it look like from a financial standpoint to suddenly give everyone with Hep C the near price equivalent of liver transplants, which we could never have dreamed of doing, if they were actual liver transplants?)*

-Pharmaceutical companies have **never been entitled to the full social value/savings of their product. Nor should they be** (apart from being impossible to predict, in the short term). Can you imagine how much aspirin, anti-septics, antibiotics, MMR vaccine would cost today, or how much more slowly medical science and public health would progress, if we were still paying huge mark ups for now basic medical breakthroughs?

-Pharmaceutical companies mention a social contract of providing a valuable product for a high initial fee to rich society. They don't touch at all on the industry role in endless free trade agreements, ever-greening/ me-too drugs and data exclusivity that are also all there, trying to change this "social contract" so that it is not "free for our children**". There is no social contract but the highest profit possible.**

-Once you **estimate "value" based on whatever calculation method you choose**, is this a **price median or a price ceiling**? If industry is driving the bus, there is no way it is going to be a ceiling used to pursue lower prices.

-**However you choose to calculate value, it will still always have arbitrary inputs** (i.e. 'willingness-to-pay amount per QALY or per life-year saved'--which is a maximum--**a hostage situation--what is the most you are willing to pay for an extra year of your life?**) and this creates upper-bound estimates that are sold to the public as "median" prices, which can be negotiated up or down. **This creates another level of exploitation**.

-In value based pricing, **patients and governments lose any upper hand they ever had**, by saying "let's pay pharma as much as we possibly can, providing we're getting good value for our large expenditure". **Given that we know that R&D spending does not equate more innovation, is that just?** What we should be saying is: "Let's pay pharmaceutical companies an amount that means they profit enough to incentivize and sustain their work".

-The main issue with **value based pricing** is that it is (whether well-intentioned or not) something that **will distract discussion from abusive monopolistic practices**.

-In addition the applicability of value based pricing to global access to medicines problems has also never been discussed or evidenced, where there is little ability to pay. It can thus only be seen, at present, as relevant to high-income countries and potentially **distracting from political pressures (which we need to build on) to reign in pharmaceutical monopolies**.

-The more pharmaceutical companies communicate this value based pricing message, the starker the fact will become that **there are lots of people who are missing out on all that value. And under the current R&D and pricing model, they always will.**

Proposed Solutions:
-**Delinkage** of the costs of research and development from the prices of drugs (*WHO Report: De-linking R&D costs from product prices James Love, Knowledge Ecology International, April 6, 2011*)*
-Use of **price restrictions**
-Use of **march-in rights** vis-à-vis the Bayh-Dole Act, in the short term

***Key issue**:
-There is **an inherent conflict of interest** in the healthcare industry (which supplies and maintains life, not expendable or elastic goods): Private sector is ultimately responsible to shareholders. Governments and health workers are ultimately responsible to their patients.

-We cannot rely on the private sector to make essential medicines affordable, nor to develop needed vs. profitable drugs. **Maximizing social benefits largely does not and will not dovetail with private benefits**.

-**Redirecting excessive pharmaceutical profit into our robust medical research infrastructure** is key (via increase NIH research and private research, **subsidized by prize incentives** that encourage innovation and competition). Resultant **patents should become public goods** in the public domain. (See commentary from economist Mariana Mazzucato.)